

***DETAILED ACTION***

The previous Office action mailed 7/20/09 is vacated in response to the interview conducted 12/28/09 and replaced with the current Office action.

The application should be reviewed for errors. Error occurs, for example, in the spelling of "Skeleonema" at least in claim 2 and in paragraph [0011].

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/09 has been entered.

Claims 1-6 and 11-12 are being considered on the merits.

***Title***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Diatoms are not "seaweed".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae. There is nothing in the as filed specification to indicate that this process is "specific" for a myriad of diatomaceous algae. Specificity is not found addressed in the instant written disclosure. In other words, there is no clear indication that "the step of applying at least one growth-limiting factor to a culture of diatomaceous algae at the end of the exponential growth phase" will result in the exclusive

"stocking" of polyunsaturated fatty acids in all diatomaceous algae. In this regard, it is not disclosed in the present record how applicant is able to communicate to the diatomaceous algae that they are to "specifically" produce polyunsaturated fatty acids.

Insertion of the limitation "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae. There are two examples in the specification, one using *Chaetoceros gracilis* and one using *Skeletonema costatum*. In each of these examples, the production of certain unsaturated fatty acids is **increased** manipulating the process conditions in a specific manner. This is not sufficient support for the new genus of limitation "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae or even from all *Chaetoceros gracilis* and *Skeletonema costatum*. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from diatomaceous algae is considered to be the insertion of new matter for the above reasons.

#### ***Response to Arguments***

Applicant's arguments and Tremblay Declaration have been fully considered but they are not deemed to be persuasive.

The data in the declaration demonstrates that in *Chaetoceros gracilis* the production of polyunsaturated acids was increased after the "silicate stress" from 13.7% to 30.3%. It is noted in this regard that the percent of saturated acids plus monounsaturated acids is greater at 36.96% than that of polyunsaturated acids at 30.3%. Therefore, the silicate stress cannot be reasonably

be concluded to result in "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae or even in *Chaetoceros gracilis* when applying "silicate stress" at days 6 or 7. Contrary to applicant's arguments there is no specificity in the methodology as claimed or in the methodology disclosed in the as-filed written disclosure. That the field of the invention is directed to a process for producing polyunsaturated fatty acids (PUFAs) and more particularly for producing omega-3 is not directly relevant to the material rejected for new matter which is directed to the insertion of the limitation of "specifically producing polyunsaturated acids" from all possible diatomaceous algae... by causing growth arrest..."

Therefore the rejection is deemed proper and it is adhered to.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 and 11-12 are vague, indefinite and confusing in the recitation of "specifically producing" and "producing specifically" polyunsaturated fatty acids". The intended meaning of this phrase is unclear in this context, even when interpreting the claim in light of the specification. See also the new matter rejection *supra*.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to the contentions regarding applicant's intentions, these intentions are not readily apparent from the as-filed specification and claims. Furthermore, these "intentions" are not substantiated by the Tremblay declaration, as discussed *supra*.

Therefore it is unclear what is intended in this context by "specifically producing" and "producing specifically" polyunsaturated fatty acids".

Thus, the rejection is deemed proper and it is adhered to.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinnis *et al.* taken with Reitan *et al.* (Journal of Phycology, Volume 30, Issue 6, Pages 972 - 979, 1994), newly cited, and Dempster and Taguchi *et al.*

The claims are directed to a method for specifically producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids.

McGinnis teaches a process of culturing diatomaceous algae for the production of polyunsaturated fatty acids wherein at least some of the diatoms where in exponential growth phase when growth limiting factors were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., page 20, col. 2, paragraph 2.

Reitan *et al.* teaches a process of culturing diatomaceous algae for the production of polyunsaturated fatty acids wherein the algae are cultured in semi-continuous culture at a low growth rate under growth limitation. Growth arrest is achieved to some extent and the quantitative content of n-3 PUFAs is increased with increasing growth limitation. See, e.g., Table 2.

In addition, Dempster teaches a process of culturing diatomaceous algae wherein at least some of the diatoms are in exponential growth phase when growth limiting factors are applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., pages 33-42.

The references differ from the claimed invention in that silicate deprivation is not disclosed and in that growth arrest does not necessarily occur at about 6 or 7 days.

However Taguchi *et al.* teach the influence of silicate deficiency on lipid synthesis by diatoms. Taguchi *et al.* studied the effects on *Chaetoceros gracilis*, *Hanstzschia* and *Cyclotella* strains and shows the favorable effects of lipid accumulation, including, of course, polyunsaturated fatty acids, after exponential growth and growth arrest. See, e.g., Fig 1.

Regarding the arrest of growth at about 6 or 7 days, there is no claim designated medium to obtain growth arrest at this time for any and all algae or even for *Chaetoceros gracilis* or *Skeletonema costatum*. It is apparent that the process in the specification in the Examples 1 and 2 requires semi-continuous culture, as in Reitan *et al.*, for example. It is noted that in Example 1 [0021], the **measurement** of fatty acids was effected 7 days after the stress, i.e., silicate deprivation, was initiated. There is no indication as to when exponential growth was attained or when the cultures reached growth arrest under semi-continuous culturing conditions. Similarly in Example 2, the **analysis** of the culture conditions was carried out 7 days after silicate deprivation was initiated.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of McGinnis *et al.* and Dempster by culturing diatomaceous algae under various growth-limiting conditions including silicate deprivation, as suggested by the teachings of Taguchi *et al.* for the expected benefit of maximizing the content of lipids in the diatomaceous algae cultures, including polyunsaturated fatty acids known to be useful in the pharmaceutical industries as well as being nutritionally essential to organisms such as oysters, fish and shrimp which are important nutrient sources for humans.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

***Response to Arguments***

Applicant's arguments as they pertain to the above rejection and the Tremblay Declaration have been fully considered but they are not deemed to be persuasive.

Applicant argues that none of the references discloses a method for specifically producing polyunsaturated fatty acids as claimed. However, the present specification similarly nowhere discloses a method for specifically producing polyunsaturated fatty acids in all diatomaceous algae or even in specific species as claimed. In addition, Reitan *et al.* demonstrate a clear correlation between nutrient limitation and an increase in quantitative PUFA production at least in *Chaetoceros* sp.. In other words, Reitan *et al.* clearly teach a process designed to enrich the amount of polyunsaturated fatty acids obtained in diatoms using growth-limitation techniques.

Regarding the Tremblay Declaration, the data in the declaration demonstrates that in *Chaetoceros gracilis* the production of polyunsaturated acids was increased after the "silicate stress" from 13.7% to 30.3%. It is noted in this regard that the percent of saturated acids plus monounsaturated acids is greater at 36.96% than that of polyunsaturated acids at 30.3%. Therefore, the silicate stress cannot be reasonably be concluded to result in "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae or even in *Chaetoceros gracilis* when applying "silicate stress" at days 6 or 7. Contrary to applicant's arguments there is no specificity in the methodology as claimed or in the methodology disclosed in the as-filed written disclosure.

It must be remembered that applicant has not shown on this record that the amount of polyunsaturated fatty acids in any diatomaceous algae is increased, or even in the particular species recited. In addition, it is apparent that the process steps of culturing diatomaceous algae in the references and as claimed are substantially the same. Therefore, one of ordinary skill in the art would have reasonably expected at the time the claimed invention was made that substantially the same results would be obtained, in the absence of evidence to the contrary.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re

Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

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/Irene Marx/  
Primary Examiner  
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